

REQUEST FOR RECONSIDERATION

Claims 1-12, 14 and 16-21 remain active in this application with claims 1-8, 10-12, 14 and 16-21 being under active consideration.

The claimed invention is directed to a hair cosmetic composition.

Hair quality can be reduced as a result of physical and chemical actions (drying, brushing, shampooing, dyeing, bleaching) and as well as by aging. Hair conditioning composition containing ceramide or glycosylceramide have been proposed but experienced difficulty in formulation and effectiveness due to a high melting point and ease of crystallization of the conditioning agent. Accordingly an improved hair cosmetic composition based on an amphipathic amide lipid is sought.

The claimed invention addresses this problem by providing a hair cosmetic composition comprising an amphipathic amide lipid and at least one of **dialkyl ethers** with alkyl groups having from 18 to 22 carbon atoms, **ethylene glycol dialkyl ethers** with alkyl groups having from 18 to 22 carbon atoms, **ethylene glycol monofatty acid esters** with an acyl group having from 18 to 22 carbon atoms, **ethylene glycol difatty acid esters** with acyl groups having from 18 to 22 carbon atoms, **fatty acid monoethanolamides** with an acyl group having from 18 to 22 carbon atoms, and **acylated  $\beta$ -alanines** with an acyl group having from 18 to 22 carbon atoms. Applicants have discovered that this combination of components, **in a ratio of from 5:1 to 1:1,000** to provide a pearlescent and stable dispersion of components in which adsorption to the hair of the amphipathic amide lipid is promoted. Such a composition is nowhere disclosed or suggested in the cited references of record.

The rejection of claims 1-8, 10-12, 14 and 16-21 under 35 U.S.C. 103(a) over Hoshina et al. EP 1,166,766 in view of Uchiyama et al. U.S. 5,876,705 is respectfully traversed.

The cited combination fails to suggest the combination of amphipathic amide lipid (A) and component (B) in a ratio of from 5:1 to 1:1,000.

Hoshino et al. had been cited for a disclosure of an external preparation which comprises an amphipathic amide lipid **but fails to disclose the claimed component (B)** nor a cationic polymer (page 3 of outstanding official action). There is no disclosure of a silicone hair conditioning agent.

Uchiyama et al. describes a conditioning shampoo comprising about 5 to about 50 wt. % of a deterative surfactant, about 0.9 to about 10 wt. % of a fatty compound, about 0.05 to about 20 wt. % of a hair conditioning agent which can be a nonvolatile dispersed silicone conditioning agent, and about 20 to about 94.05 wt. % of water (column 2, lines 23-41). In order to assist with dispersion of the silicone hair conditioning agent, a silicone suspending agent may be added (column 21, lines 48-51). Ethylene glycol stearate is described as a preferred silicone dispersant for suspending the silicone hair conditioning agent (column 21, lines 62-65). There is no disclosure of an amphipathic amide lipid. Thus, Uchiyama et al.'s reason for including ethylene glycol stearate in a conditioning shampoo composition would be to act as **a suspending agent for a silicone hair conditioning agent**.

The two references separately disclose the two components of the claimed composition, but do not suggest the combination of the two in a hair cosmetic composition.

In contrast, the claimed invention is directed to a hair cosmetic composition comprising an amphipathic amide lipid (A) and a component (B) in a ratio of 5:1 to 1:1,000. The claims recite a ratio of components (A):(B) of 5:1 to 1:1,000.

It would not have been obvious to include components (A) and (B) in a hair cosmetic composition in a ratio of 5:1 to 1:1,000 as the cited art does not disclose any relationship between the two components.

As noted previously, Uchiyama et al. describe that ethylene glycol stearate is a dispersant for **a silicone hair conditioning agent**. The dermatologic preparation of Hoshino et al. fails to disclose a silicone hair conditioning agent. Thus, there would be no motivation to add the dispersant for a silicone hair conditioning agent of Uchiyama et al. into the dermatologic preparation of Hoshino et al. as suggest in the official action, at an (A):(B) ratio of 5:1 to 1:1,000, as Hoshino et al.'s composition does not contain a silicone hair conditioning agent. Where is the motivation to have a ratio of amphipathic amide lipid to dispersant for a silicone hair conditioning agent of 5:1 to 1:1,000 in a composition which does not contain a silicone hair conditioning agent? There would be no motivation to have a relative ratio of components when the motivation of including a dispersant for a silicone hair conditioning agent is not present. Accordingly, the claimed invention in which the amphipathic amide lipid and component (B) are present in a ratio of 5:1 to 1:1,000 would not have been obvious.

Page 3 of the official action repeats the assertion that the claimed invention is little more than the combination of conventional hair care agents. None the less, on page 5 of the outstanding official action, the action reasons that the amphipathic amide lipid of EP '766 and the silicone hair conditioning agent of U.S. '705 are both "oily substances" such that one of ordinary skill in the art would be motivated to use the silicone suspending agent of U.S. '705 to disperse the amphipathic amide lipid of EP '766. The office action further reasons that the conventional amounts of amphipathic amide lipid used in EP '766 when combined with the conventional amount of silicone suspending agent, would necessarily meet the claimed ratio of 5:1 to 1:1,000.

*No Motivation To Include The Silicone Suspending Agent Of U.S. '705 In The  
Silicone Devoid Composition Of EP '766*

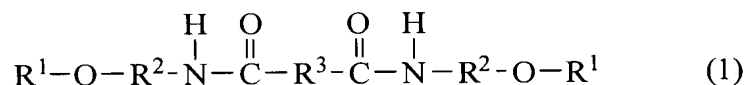
As previously noted the composition of EP '766 fails to disclose a silicone hair conditioning agent. None the less, the office action reasons that the common identity as "oily substances" would lead one of ordinary skill in the art to use the silicone suspending agent of U.S. '705 as a suspension aid for the amphipathic amide lipid of EP '766.

*An Amphipathic Amide Lipid Is Structurally Different From A Silicone Hair  
Conditioning Agent*

There is no structural similarity between an amphipathic amide lipid and a silicone hair conditioning agent such that suspension of one does not suggest suspension of the other.

The silicone hair conditioning agent of U.S. '705 is non-volatile and preferably has a boiling point of about 250° or higher (column 12, lines 41-47). The agent has a viscosity at 25°C of from 1,000 to about 2,000,000 centistokes (column 12, lines 55-57) and includes structures of polyalkyl siloxanes, polyaryl siloxanes, polyalkylaryl siloxanes, polyether siloxane copolymers and mixtures thereof (column 12, lines 63-66). Thus, the silicone hair conditioning agent is a non-volatile polymeric silicone.

In contrast, the amphipathic amide lipid of EP '766 has a completely different structure of



The structure has no silicon atoms and does not have a polymeric structure. Due to the stark differences in structure, those of ordinary skill in the art would not be motivated to use the silicone suspending agent of U.S. '705 to suspend the amphipathic amide lipid of EP

‘766. The unsubstantiated assertions that the two materials are common as oily substances is not sufficient.

Further, there is no suggestion in EP ‘766 that an amphipathic amide lipid is in need of suspension assistance by use of a suspending agent.

Nowhere in EP ‘766 is there a disclosure that the amphipathic amide lipid is in need of suspension stabilization. Nowhere does EP ‘766 describe the amphipathic amide lipid as in the form of a suspension. There is only a disclosure at paragraph [0020] of forms as w/o and o/w emulsion cosmetics, creams, cosmetic milky lotions, cosmetic lotion, oily cosmetic lipstick, foundation, bath agent skin cleanser, nail treatment and hair cosmetics and that the cosmetic containing the diamide derivative may be formulated into an aqueous solution, ethanol solution, emulsion, suspension, gel, solid, aerosol or powder without limitation [0027]. Thus, there is no suggestion of the need to assist suspension of the amphipathic amide lipid such that there would be no motivation to include the silicone suspending agent of U.S. ‘705 in the composition of EP ‘766. Applicants disclosure on page 3, lines 20-21 is irrelevant to the expectation of those of ordinary skill in the art as applicants’ specification is not available as prior art against the claimed invention.

*A Ratio Of 5:1 to 1:1,000 Does Not Flow From Overlapping Concentrations*

The office action reasons that the content of amphipathic amide lipid of 0.001 to 50 wt. % according to EP ‘766 when coupled with the disclose content of 0.1 to 10 wt. % of silicone suspending agent used to suspend a silicone hair conditioning agent would meet the claimed range of 5:1 to 1:1,000.

Notwithstanding the lack of motivation to even include the silicone suspending agent of U.S. ‘705 in the silicone lacking composition of EP ‘766, the claimed ratio would not be met. Based on the endpoints of concentrations for the two agents one could calculate a range

of ratios of 500:1 to 1:10,000. Such a broad range fails to suggest the claimed range of 5:1 to 1:1,000.

Withdrawal of the rejection under 35 U.S.C. 103(a) is respectfully requested.

Moreover, applicants observe an enhancement in hair penetration of the amphipathic amide lipid when combined with component (B). The examiner's attention is again directed to Table 1 on page 29 of applicants' specification which evaluates the hair conditioning performance of the claimed combination of components (A) and (B) as compared with compositions lacking component (B) (comparative example 1) or lacking component (A) (comparative example 2). For the examiner's convenience a portion of the data is reproduced below:

Table 1

(Unit of content is wt.%)

|   |   | Examples     |              |              | Comparative Examples |              |
|---|---|--------------|--------------|--------------|----------------------|--------------|
|   |   | 1            | 2            | 3            | 1                    | 2            |
| (A)   | Amphipathic amide lipid A                       | 0.5          | -            | 0.5          | -                    | -            |
|   | Amphipathic amide lipid B                       | -            | 0.1          | -            | 2                    | -            |
| (B)   | Ethylene glycol distearyl ester                 | 2            | -            | -            | -                    | 1            |
|   | Distearyl ether                                 | -            | 2            | 2            | -                    | -            |
| Others                                      | Sodium polyoxyethylene (2) lauryl ether sulfate | 10           | 10           | 10           | 10                   | 10           |
|   | Sodium lauryl sulfate                           | 5            | 5            | 5            | 5                    | 5            |
|   | Cocoyl monoethanolamide                         | 0.5          | 0.5          | 0.5          | 0.5                  | 0.5          |
|   | Cationic hydroxyethylcellulose                  | 0.3          | 0.3          | 0.3          | 0.3                  | 0.3          |
|   | Cationic guar gum                               | 0.5          | 0.5          | 0.5          | 0.5                  | 0.5          |
|   | 50 wt.% aq. NaOH soln/50 wt.% citric acid       | q.s. *       | q.s. *       | q.s. *       | q.s. *               | q.s. *       |
|   | Purified water                                  | Bal-<br>ance | Bala-<br>nce | Bala-<br>nce | Bala-<br>nce         | Bala-<br>nce |
| pH  |   | 3.5          | 3.5          | 3            | 3.5                  | 3.5          |
| Buffering capacity (NaOH-gram equivalent/L) |   | 0.02         | 0.01         | 0.01         | 0.01                 | 0.01         |
| Eval-<br>uation                             | Resilience and strength of hair                 | 3.1          | 2.7          | 3.9          | 1.8                  | 1.6          |
|   | Smoothness of hair                              | 3.8          | 3.6          | 3.8          | 2.1                  | 1.2          |
|   | Moist feeling of hair                           | 3.8          | 3.7          | 3.8          | 2.2                  | 1.0          |
|   | Storage stability (50°C × 1 month)              | A            | A            | A            | C                    | A            |

\* : amount enough for pH adjustment

Example 1 containing amphipathic amide lipid A and ethylene glycol distearyl ester exhibited high evaluation for hair conditioning performance in terms of resilience and strength of hair, smoothness of hair and moist feeling of hair plus, no change in appearance upon storage at 50°C for one month.

Example 2 containing amphipathic amide lipid B and distearyl ether exhibited high evaluation for hair conditioning performance in terms of resilience and strength of hair, smoothness of hair and moist feeling of hair plus, no change in appearance upon storage at 50°C for one month.

In contrast, comparative example 1, having amphipathic amide lipid B but no ethylene glycol distearyl ester exhibited lower hair care performance and exhibited separation or gelation upon storage at 50°C for one month. Applicants further note that example 2 and comparative example 1 each contained the same amphipathic amide lipid B, but example 2 which further comprised distearyl ether, but a smaller amount of amphipathic amide lipid B demonstrated enhanced resilience and strength of hair, smoothness of hair and moisture feeling of hair.

Page 7 of the official action asserts applicants' observation of smoothness and moist feeling to be expected as a result of using an amphipathic amide lipid. However, the **degree of enhancement** of smoothness and moist feeling for example 2 with only 0.1 wt.% of amphipathic amide lipid B was far in excess to that of comparative example 1 which contained 20 x the amount of amphipathic amide lipid B, at 2 wt. %. Thus, through the combination of amphipathic amide lipid and component (B), applicants are able to observe an improved hair protecting effect which is not suggested in the cited art of record.

Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness *In re Chupp* 816, F2d. 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir 1987). M.P.E.P. §§ 2145

Further, contrary to the assertions in the official action that applicants' observation of enhanced dispersion stability for the amphipathic amide lipid is expected, applicants' observance of enhanced dispersion stability is not suggested by the cited art since the silicone suspending agent for a silicone hair conditioning agent would not have been expected to enhance the dispersion stability of an amphipathic amide lipid due to the differences in structure.

The examiner's attention is further directed to page 3 of applicants' specification which states:

The present **inventors have found** that incorporation of **a compound serving as a pearling agent together with an amphipathic amide lipid** serving as a protecting base in a hair cosmetic composition **improves the dispersion stability** of the amphipathic amide lipid and heightens adsorption of it to the hair to **improve the hair protecting effect** and at the same time, imparts a pleasant feel to hair significantly.

Such statement **must be treated as objectively true, unless** the examiner has reasons, based on sound scientific principles, to doubt the objective truth of applicants' specification.

The burden is on the Patent Office to provide reasons based on scientific principles, to doubt the objective enablement of Applicant's claimed invention. Applicant's disclosure **must be taken as in compliance** with the enabling requirement under 35 USC 112, first paragraph, **unless, there is reason to doubt the objective truth of the statements contained therein.** (*In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)) M.P.E.P. §§2163.04.

The examiner has provided no basis to doubt the objective truth of applicants' disclosure and demonstration such that the claimed demonstration is believed to be commensurate in scope with the claimed invention.

As the cited references fail to provide any motivation to have an amphipathic amide lipid and component (B) present in a ratio of 5:1 to 1:1,000, the claimed invention would not have been rendered obvious and withdrawal of the rejection under 35 U.S.C. 103(a) is respectfully requested.

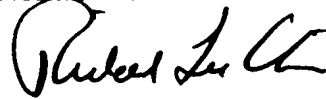


Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

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